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Our file: 80166

Agents for disinfecting and cleaning surfaces

The present invention relates to agents for disinfecting and cleaning surfaces, wherein an invert soap having at least one branched alkyl chain, is utilized. In particular, the invention pertains to agents for disinfecting and cleaning surfaces, wherein the invert soap utilized has two short-chain alkyl groups and two long-chain alkyl groups.

Surfaces are constantly contaminated with micro-organisms due to exposure to the environment. The presence of such micro-organisms on floors or other surfaces is not desired in particular areas, such as e.g. sanitations, hospitals or swimming pools, or may even be partially hazardous, since there is a danger of an infection and a transmission of germs, respectively, to persons present there. Consequently, such surfaces are treated with disinfectants, which are added to a conventional detergent, which is used for cleaning surfaces. A disadvantage of the known disinfectants resides in that even though a variety of bacteria are killed, but however the efficacy towards viruses is often inadequate.

The requirements for decontamination of surfaces of medical devices, such as dental suction devices, endoscopes or other hollow bodies, which are introduced into living organisms during surgery are even higher. Therefore, these devices have to be cleaned from contaminating material, such as body fluids, e.g. blood or secretory fluid, each time when used. In order to prevent a transmission of pathogenic micro-organisms, such as bacteria, funghi and/or viruses to patients, treated subsequently, these agents have to be removed, killed or at least inactivated.

During the last few years specific processing devices, such as specific "washing maschines" for endoscopes, have been utilized for cleansing and disinfecting such devices, so as to avoid a direct contact of the devices with the personnel during the entire process.

These apparatuses are run in a two step process at ambient temperature. In a first step the devices charged thereto are subjected to a treatment with known detergents, such as anionic or non-ionic surfactants and enzymes, respectively, to degrade biological contaminations. In a second step they are contacted with disinfectants on the basis of aldehydes.

However, it has been shown that the time required for cleansing and decontaminating the

devices by these apparatuses took too long, in order to have a cleaned and disinfected device available during clinical tests whenever required. In addition, the devices could have been contaminated with germs present in the water utilized for rinsing, which the germs could have multiplied during inappropriate storage of the devices and therefore could render it infectious for a patient.

Due to these problems, the two-step process for cleaning and decontaminating medical devices is run at elevated temperatures up to 60 °C maximum. To this end, the goods charged are introduced into a washing department within the apparatus, the temperature of the cleansing bath is raised and, during step one, a detergent is dosed into the cleansing bath at a particular temperature. After finalizing the cleaning step, the cleansing bath is discharged and in a second step fresh water supplemented with a disinfectant is added such that after a certain processing time period at a chosen temperature the devices should be free of pathogenic agents and should be degerminated. After discharging the apparatus the devices are rinsed with water once or twice, whereupon the devices are ready to use them again.

The agents used for this type of processing are variants of the products used for the processing at ambient temperature.

Normally, combinations of non-ionic surfactants together with complexing agents and enzymes are used as cleansing agents. All of those cleansing agents strive to improve the moistening of the devices' hydrophobic surfaces and thus to increase the volume of the water that passes through the occasionally existing narrow or confined lumina of such devices during processing.

The disinfectants utilized in this process are all based on aldehydes. Aldehydes are of low corrosive nature and enable inactivation of a variety of micro-organisms. However, the efficacy of aldehydes towards spores is extremely low.

Even though particular viruses, such as picorna-viruses, as well as myco-bacteria may be inactivated simply by choosing temperatures of up to 60 °C during the known processes, an inactivation of other viruses, such as Hepatitis B viruses, is not sufficiently possible by applying the presently known disinfecting methods.

Further, the known processes suffer from the disadvantage that the aldehydes utilized fix blood or proteins that had not been entirely removed during the first cleansing step onto the surface of the devices. Thus, it has been found that such a fixation often occurs on the surfaces of the confined lumina so that the residual contamination is not noticed upon an unspecific visual

inspection or by rinsing through a wide lumen of the devices. As is known, pathogenic germs may survive such processing in such residual contaminations and may represent an infectious agent during subsequent use of the device for the patient. Additionally it has been found that in spite of decontaminating the devices according to the process illustrated above a transmission of germs derived from a patient that had been treated with that device to a subsequent patient may occur.

An additional shortcomings of conventional methods resides in that the personnel is confronted with aldehyde containing products. For example, in case the apparatus is untimely opened due to malfunctions or in case the aeration of the apparatus is not sufficiently ensured, aldehyde containing vapors may get to the ambient air. In addition, during charging the apparatus with fresh disinfectants the personnel may come into contact with concentrated aldehydes.

An object of the present invention resides in reducing the processing time of medical devices as well as reducing the risk the personnel is subjected when dealing with disinfectants utilized.

This objective has been achieved by providing an agent for disinfecting decontaminated surfaces, which contains an invert soap having at least one branched alkyl chain.

According to a preferred embodiment said at least one branched alkyl chain has between 4 and 20 carbon atoms, preferably 6 to 16, more preferably between 8 and 14 carbon atoms. Most preferred the branched alkyl chain is a branched C_8-C_{12}-alkyl chain.

According to another preferred embodiment the invert soap contains at least another long-chain alkyl group having 4 to 20 carbon atoms, and exhibits furthermore two short-chained alkyl groups, which preferably are 2 methyl groups.

It has been found that such invert soaps particularly are suitable for cleansing surfaces. The disinfectants produced therewith are non-toxic and exhibit an extremely high microbicide activity against bacteria, funghi and all known species of viruses. Surprisingly, also spores may be inactivated using these agents.

Due to the strongly microbicide activity, the processing time for the devices may substantially be reduced. This is due to - inter alia - the bivalent properties of the agents according to the present invention. Accordingly, a one step processing of the devices may be carried out, since the agents used exhibit cleansing as well as excellent microbicide properties. A fixation of contaminations in narrow and confined lumina of the devices does not occur either, with the effect that the danger of transmitting an infection from one patient to subsequent

patients is minimized.

Moreover, the disinfectants of the present invention may generally be applied for the disinfective cleansing of all types of surfaces, such as floors, in particular floors of hospitals or swimming pools, or for combating fungal infection on the skin, such as athlete's foot, due to the tolerance of the skin. Thus, the health risk of the personnel or the person using the agent may be minimized.

The disinfectants of the present invention may be used in the processing apparatuses commonly put to use or even in open containers at temperatures of from ambient temperature to about 75 °C. Having a view to the medical device to be handled treating temperatures of from about 40°C to 65°C or about 50°C to 60°C are preferred.

During a processing of devices using the agents of the present invention sterilized water is introduced into the processing apparatus if necessary, optionally after a pre-cleansing step. In order to improve the efficacy of the process a disinfectant may be used during the pre-cleansing step, which needs, however, not to be identical to the agent of the present invention.

The water utilized during processing may have any hardness, which does not negatively affect the efficacy of the agents of the present invention. Having a view to the formation of a deposit onto the devices or in the apparatus it is possible to adapt the recipe of the applied agents of the present invention such that a calcification does not occur. The agents suitable for this purpose are well known to the skilled person. The use of desalted water may likewise be envisaged.

The agent of the present invention is dosed into the cold or already heated processing bath, which may be effected manually or by means of a automatic control system. Depending on the situation of the apparatus put to use and based on his common technical skill the skilled person will decide on the appropriate dosage of the agent of the present invention to be utilized as well as adapt the temperature accordingly and determine, whether the temperature of the bath shall be raised immediately after dosing or whether it shall be maintained for a predetermined period of time.

In carrying out the process for processing medical devices it is preferred that the temperature of the bath is raised to the temperature for disinfecting without changing the bath, while maintaining it by agitation of the water and cleansing and by disinfecting the devices for a particular period of time. After discharging the cleansing and disinfecting bath the device is then rinsed with clear and preferably conditioned water, i.e. water having a reduced number of germs

or being essentially aseptic, so as to be ready for further use. A subsequent drying of the medical device after rinsing may be effected without being necessary.

The specific conduct of the process of the present invention is determined by the assembly of the processing apparatus used and by the type of devices to be processed. In theory a processing at elevated temperature of the processing bath may also be performed manually.

For disinfecting and cleaning of surfaces, such as floors, the agent may simply be added to the washing fluid, wherein the agent will enable a high cleaning and degerminating activity. It has been shown that the agent of the present invention is well accepted by the skin and does not tend to foam.

The agent of the present invention contains an invert soap, which has at least one branched alkyl group having 4 to 20 carbon atoms. The branchings may be at any position of the alkyl chain and comprise methyl, ethyl, propyl or butyl branches, respectively, on the main chain. In addition, more than only one branching may also be present, such as e.g. two or more of methyl, ethyl or propyl branches or mixtures thereof, wherein the branches may be present on the same or on different carbon atoms on the main chain. In particular preferred branched chains comprise C_8-C_{12}-alkyl groups, that contain methyl and/or ethyl branches. A most preferred example of a branched alkyl group is isononyl, which may be obtained from LONZA under the product name "Bardac 2170".

The other residues of the positively charged nitrogen atom may be branched or also linear alkyl groups containing from 1 to about 20 carbon atoms, e.g. methyl, ethyl, propyl, butyl, pentyl, hexyl, heptyl, octyl, nonyl, decyl, undecyl, dodecyl, tridecyl, tetradecyl, pentadecyl, hexadecyl, heptadecyl, octadecyl, nonadecyl and dodecaacyl groups. In addition aryl groups and aralkyl groups, respectively, such as benzyl or phenyl groups, or oxyalkyl groups may be bound to the nitrogen atom.

Invert soaps are preferred, wherein the branched but also the linear alkyl groups contain independently of from 4 to 20 carbon atoms, preferably between 6 to 16, particularly preferred between 8 and 14, more particularly preferred between 8 and 12 carbon atoms. A combination of branched and linear C_8-C_{12}-alkyl chains has been shown to be particularly effective. The alkyl groups may be unsaturated, with saturated alkyl groups being preferred.

According to a preferred embodiment the invert soaps comprise two long-chain alkyl groups each with more than 4 carbon atoms, with at least one of them being branched, and two short-chain alkyl groups each with 1 to 3 carbon atoms, i.e. methyl, ethyl and/or propyl. The

long-chain and short-chain, respectively, alkyl groups on the nitrogen atom may be identical or different, with the proviso that at least one branched alkyl group is bound to the nitrogen atom.

The synthesis of such invert soaps is known in the art and may be carried out by any person skilled in the field of organic chemistry.

As the counter-ions anorganic ions may be used, such as fluoride, chloride, bromide or iodide, as well as organic anions, such as e.g. citrate, propionate and ethyl sulfate or methyl sulfate, respectively. During processing the ion is considered as the counter-ion that is present during application of the agent of the present invention in a large excess or alone and affects the properties of the product and not the ion that saturates the positive charge of the nitrogen atom upon addition of the microbicide agent. However, on the basis of his own technical knowledge and by considering the circumstances and objectives the skilled person will use the appropriate counter-ion.

The invert soap is solved in a solvent to improve application, e.g. water, with additional surfactants, anti-corrosive agents, foam-reducing agents, acids and bases, respectively, for adjusting the desired pH, colourants and/or fragrances may be present as well.

Apart from using the above mentioned invert soaps the additional use of other, commonly known microbicide substances is likewise possible, such as e.g. aldehydes, in particular glutaraldehyde, benzalkoniumchloride, didecylmethyloxethylammonium propionate, polyhexamethylene biguanide and its salts, chlorhexidine and its salts, chlorine and chlorine generating agents, such as chloramine T, and/or per-compounds, such as e.g. potassium-monopersulfate or peracetic acid, azine derivates, such as e.g. hexahydrotriazine, microbicide organic acids, such as e.g. apple acid, sorbic acid, salicylic acid or benzoic acid.

The variety or the single microbicide agent/s are/is formulated into the product in an amount such that by using a conventional dosage of the product a disinfection of the medical device during the processing in the processing apparatus is ensured. This may be determined first of all by using contaminated screws or pieces of rubber-tubes.

During processing of medical devices the commonly used dosage regimen of the agents of the present invention are usually about 100 to 1000 ppm, preferably 200 to 600 ppm, most preferred 300 to 500 ppm, based on the entire bath, with the temperature of the bath being at ambient temperature, preferably at elevated temperatures of up to 75 °C and with the time being maintained between 5 minutes and 10 minutes. With such a dosage regime about 50 to 400 ppm of non-ionic surfactants, 50 to 800 ppm of anorganic or organic acids and small amounts of

corrosion inhibitors, foam-reducing agents, parfume oils or dyes may be dosed.

Advantageously, the surfactants used in the product of the present invention are selected such that the cloud temperature of the agent in an aqueous medium is at the concentration of use at about the dosage temperature, at which the agent is added to the bath. This may be easily determined by the person skilled in the art on the basis of his general knowledge.

For treating surfaces, such as floors in hospitals and the like, the concentration of the agent of the present invention in the washing fluid may be appropriately increased and is in the range of up to 1-2 %. Due to the low steam pressure of the agent high concentrations thereof in the washing fluid is not detrimental for the personnel, since essentially no transfer in the ambient air occurs. Also a contact of diluted solutions with the skin is essentially not detrimental. The washing fluid for disinfecting and cleansing (degerminating cleansing) may easily be prepared by dosing the agent from a concentrated solution. Even applying a spray is possible, which may be used in particular for the treatment of athlete's foot. However, sprays may likewise be applied for the treatment of tables and the like.

The following examples illustrate the invention and are not to be construed to limit the invention. Examples 2 to 5 are for comparative purposes and show the superior properties of the products of the present invention during processing of devices.

Example 1

The disinfectant formulations 1 to 9, listed in the Table 1 as shown below, have been prepared. In the formulations 2 to 5 no invert soap has been added.

Table 1

Disinfectant fomulations

formulation	1	2	3	4	5	6	7	8	9
decylisononyldimethyl-ammoniumchloride	3,00		4,00	8,00		2,00			
decylisononylmethyloxethyl-ammoniumproprionate								4,00	
didecyldimethylammoniumchloride		2,00			4,00				
dioctyldimethylammoniumchloride	2,00	3,00							4,00
ethylhexylisotridecyldimethyl-ammoniumchloride							5,00		
glutaraldehyde 50%									10,00
hexahydrotriazine						8,00			
citric acid		10,00	10,00	10,00	10,00			10,00	
acetic acid	5,00						5,00		5,00
1,2-propanediol	30,00	30,00	30,00	30,00	30,00	30,00	30,00	30,00	30,00
isotricecyl alcohol EO-PO	2,00	2,00	2,00	2,00	2,00		2,00	2,00	2,00
anti-foaming agent 3471		0,10		0,10	0,10		0,10	0,10	0,10

sodiumhydroxide solution 25%	18,00	36,00	36,00	36,00	36,00		18,00	36,00	10,00
benzotriazole	0,20	0,20	0,20	0,20	0,20		2,00	2,00	0,20
butindiole	0,50	0,50	0,50	0,50	0,50		0,50	0,50	0,50
water to 100									

The products are all clear and stable for at least one week even at elevated temperature of 50°C.

The capacity of the formulations to disintegrate blood has been examined on rubber tubes with wether blood that had been made coagulable and was heparinized. A thin blood layer has been deposited onto the tube pieces and left to dry for one hour.

The tube pieces were then immersed at a processing temperature of 60°C for 10 minutes in the disinfectant solution, taken after expiry of the time period and assessed after drying.

A relative scale of 1 to 5, taking water as a reference, has been drawn up.

Table II

	1	2	3	4	5	6	7	8	9	H_2O
meas.	2	5	3	3	5	1	2	2	2	1

As may be derived from Table II, above, the cleaning activity of the exemplary agents is improved as compared to the comparative formulations.

Example 2

The formulations shown in Table I have been examined for their efficacy in a Germ-Carrier-Assay using screws contaminated by Streptococcus faecium as the testing germ.

The assay has been performed at 50°C with the contamination being according to CEN. After incubation it was assessed, whether there were germs being capable to survive in the contamination on the screws after treatment or not. The number indicated shows the period of treatment required in minutes, after which no growth was detectable.

Table 3

	1	2	3	4	5	6	7	8	9	H_2O
min	6	10	7	7	10	5	5	5	6	20

The obvious superiority of the agent of the present invention as compared to the agents according to the prior art becomes evident.

Example 3

50 processing experiments have been carried out with different flexible endoscopes. During processing cleansing and disinfection has been carried out simultaneously in one bath. After processing the endoscopes have been analyzed for contaminations using swabs for preparing smears. The swabs were transferred to a culture medium which were incubated at 37°C for 24 h. The formulations according to the present invention did not show any residual contamination.